

RULEMAKING NOTICE FORM

Notice Number 2016-176	Rule Number	He-P 4035 (various)
1. Agency Name & Address: NH Dept. of Health & Human Services Division of Public Health Services Radiological Health Section (RHS) 29 Hazen Drive Concord, NH 03301	2. RSA Authority: 3. Federal Authority: 4. Type of Action: Adoption Amendment Repeal Readoption Readoption w/amendment	<div style="border-bottom: 1px solid black; padding-bottom: 2px; text-align: center;">RSA 125-F:5, IV & V</div> <div style="border-bottom: 1px solid black; padding-bottom: 2px; text-align: center;">Section 274 of the Atomic Energy Act of 1954 as amended</div> <div style="border-bottom: 1px solid black; padding-bottom: 2px; text-align: center;">_____</div> <div style="border-bottom: 1px solid black; padding-bottom: 2px; text-align: center;">X</div> <div style="border-bottom: 1px solid black; padding-bottom: 2px; text-align: center;">_____</div> <div style="border-bottom: 1px solid black; padding-bottom: 2px; text-align: center;">_____</div> <div style="border-bottom: 1px solid black; padding-bottom: 2px; text-align: center;">_____</div>

5. Short Title: **Use of Byproduct Materials in the Healing Arts Recordkeeping, Accountability, Safety Instructions, and Training.**

6. (a) Summary of what the rule says and of any proposed amendments:

The Department of Health and Human Services, Radiological Health Section (DHHS/RHS) is proposing to amend various sections of He-P 4035 consistent with Nuclear Regulatory Commission (NRC) recommendations made during its recent review of the rule. He-P 4035 was readopted effective January 15, 2016, and sections He-P 4035.13 and He-P 4035.73 were further amended effective May 25, 2016.

He-P 4035 states requirements for: medical production, preparation, compounding, and use of byproduct material in the healing arts, issuing licenses authorizing medical use of radionuclides and byproduct material, and radiation safety of workers, the general public, patients, and human research subjects. Proposed amendments to the rule correct internal references, clarify requirements, and add the requirement that a written directive be signed and dated by an authorized user.

Other proposed amendments to He-P 4035 include:

- **Adding the requirement that the written directive be signed by an authorized user in He-P 4035.13(b)(4);**
- **Adding the requirement that the licensee send a copy of the annotated report of a medical event to the referring physician in He-P 4035.14(a)(7);**
- **Adding contact with byproduct material radiation to He-P 4035.38(a) so that an additional dose equivalent includes byproduct material radiation and not just contact with the material itself;**
- **Clarifying the safety instructions for safe handling and shielding of brachytherapy sources in He-P 4035.42(c)(2);**
- **Specifying the subject of He-P 4035.44(a)(2) as human research subjects or patients;**
- **Adding the requirement in He-P 4035.55(b) that procedures be written;**
- **Adding spot checks of radiation monitors in He-P 4035.55(s)(6);**

- Specifying that the procedures referred to in He-P 4035.66(b) be those requiring a written directive;
- Specifying the type of training, classroom and laboratory training in He-P 4035.68 and He-P 4035.74; and
- Correcting internal references in sections He-P 4035.55, 4035.66, and 4035.70.

6. (b) Brief description of the groups affected:

Those affected by the rule include those who produce, prepare, compound, use and are trained to use byproduct material for medical purposes and in the healing arts. The rule also affects the issuance of licenses authorizing the medical use of byproduct material which provides for the radiation safety of workers, and the safety of patients, human research subjects and the general public.

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

<u>RULE</u>	<u>STATUTE OR FEDERAL REGULATION IMPLEMENTED</u>
He-P 4035.13(b)(4)	10 CFR 35.40, 35.41, 35.100, 35.2040, 35.2041
He-P 4035.14(a) intro. & (a)(7)	10 CFR 35.3045
He-P 4035.35 intro.(b) & (c)	10 CFR 35.300
He-P 4035.38(a)	10 CFR 35.3047
He-P 4035.42(a),(c) intro. & (c)(2)	10 CFR 35.410, 35.2310
He-P 4035.44(a) intro. & (a)(2)	10 CFR 35.406, 35.2406
He-P 4035.55(b), (e), (r), and (s) intro., (s)(5), (s)(6)	10 CFR 35.642, 35.643, 35.645, 35.2642, 35.2643, 35.2645
He-P 4035.56(b)	10 CFR 35.652, 35.2652
He-P 4035.66(b) intro., (b)(2), (g), (i) intro., (i)(2), & (i)(4)	10 CFR 35.392, 35.394, 35.396
He-P 4035.68 intro. & (b) intro.	10 CFR 35.590
He-P 4035.70 intro., (a) intro., (a)(5) & (c)	10 CFR 35.51
He-P 4035.74 intro., (c) intro., (c)(1) intro., (c)(1)a. & b.	10 CFR 35.44

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name:	Catherine Bernhard	Title:	Rules Coordinator
Address:	Dept. of Health & Human Services Administrative Rules Unit 129 Pleasant St. Concord, NH 03301	Phone #:	271-9374
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TTY/TDD Access: Relay NH 1-800-735-2964 or dial 711 (in NH)

The proposed rules may be viewed and downloaded at:
<http://www.dhhs.nh.gov/oos/aru/comment.htm>

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **Friday, October 28, 2016**

☒ Fax

☒ E-mail

☐ Other format (specify):

9. Public hearing scheduled for:

Date and Time: **Friday, October 21, 2016 at 1:00 p.m.**

Place: **DHHS Brown Bldg., Room 232, 129 Pleasant St., Concord, NH**

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant)

FIS # **16:173**, dated **08/31/16**

1. Comparison of the costs of the proposed rule(s) to the existing rule(s):

There is no difference in cost when comparing the proposed rules to the existing rules.

2. Cite the Federal mandate. Identify the impact of state funds:

The State of New Hampshire is an agreement state with the U.S. Nuclear Regulatory Commission (NRC), pursuant to section 274b of the Atomic Energy Act of 1954, as amended. As such, the State is required to have a program in place that is adequate and compatible with federal regulations, which these rules address. There is no effect on State funds associated with any of the proposed rules.

3. Cost and benefits of the proposed rule(s):

A. To State general or State special funds:

None.

B. To State citizens and political subdivisions:

None.

C. To independently owned businesses:

None.

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

The proposed rules modify an existing program or responsibility, but do not mandate any fees, duties or expenditures on the political subdivisions of the state, and therefore do not violate Part I, Article 28-a of the N.H. Constitution.

Amend He-P 4035.13, effective 1-15-16 (Document #11011), as amended effective 5-25-16 (Document #11108), by amending (b)(4), so that (b) intro. and (b)(4) are cited and read as follows:

Part He-P 4035 USE OF BYPRODUCT MATERIALS IN THE HEALING ARTS

He-P 4035.13 Quality Management Program and Written Directives.

(b) The quality management program shall include written policies and procedures to meet the following specific objectives:

(4) That each administration shall be in accordance with the written directive. The written directive shall be dated and signed by an authorized user. The written directive shall contain the patient or human research subject's name and the following information:

Amend He-P 4035.14, effective 1-15-16 (Document #11011), by inserting (a)(7), so that (a) intro and (a)(7) are cited and read as follows:

He-P 4035.14 Records, Notifications, and Reports of Medical Events.

(a) For a medical event, the licensee shall:

(7) Send copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

Amend He-P 4035.35(b) and (c), effective 1-15-16 (Document #11011), so that He-P 4035.35 intro., (b), and (c) are cited and read as follows:

He-P 4035.35 Use of Unsealed Byproduct Material—Written Directive Required. A licensee shall use any unsealed byproduct material prepared for medical use and for which a written directive is required that is:

(b) ~~Prepared by, excluding (a) above~~Excluding production of PET radionuclides, prepared by:

(c) Obtained from and prepared by a DHHS/RHS licensee, or an equivalent agreement state, or a Nuclear Regulatory Commission licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

Amend He-P 4035.38(a), effective 1-15-16 (Document #11011), cited to and to read as follows:

He-P 4035.38 Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.

(a) A licensee shall report any dose to an embryo/fetus, that is greater than 50 millisieverts (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

Amend He-P 4035.42(a) and (c)(2), effective 1-15-16 (Document #11011), so that (a), (c) intro., and (c)(2) are cited and read as follows:

He-P 4035.42 Safety Instruction for Use of Brachytherapy Sources.

(a) The licensee shall provide [radiation safety](#) instruction (commensurate with the duties of the personnel) initially to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under He-P 4035.25.

(c) To satisfy He-P 4035.42(a), the instruction shall describe:

(2) The safe handling and shielding instructions ~~in case of a dislodged source~~;

Amend He-P 4035.44(a)(2), effective 1-15-16 (Document #11011), so that (a) intro. and (a)(2) are cited and read as follows:

He-P 4035.44 Brachytherapy Sources Accountability.

(a) A licensee shall:

(2) As soon as possible after removing sources from a patient or a human [research](#) subject, return brachytherapy sources to a secure storage area.

Change the section heading for He-P 4035.48, effective 1-15-16 (Document #11011), to read as follows:

He-P 4035.48 Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, or Gamma Stereotactic Radiosurgery Units.

Amend He-P 4035.55, effective 1-15-16 (Document #11011), by amending (b), (e), (r), and (s)(5) and inserting (s)(6), so that (b), (e), (r), (s) intro., (s)(5) and (s)(6) are cited and to read as follows:

He-P 4035.55 Periodic Spot-Checks for Teletherapy Units, Remote Afterloader Units, and Gamma Stereotactic Radiosurgery Units.

(b) A licensee shall perform spot-checks required by He-P 4035.55(a) in accordance with [written](#) procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(e) A licensee shall lock the control console in the “off” position if ~~any system malfunctions~~ [it indicates the malfunction of any system](#), and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(r) To satisfy the requirements of He-P 4035.55(~~ep~~)(1), spot-checks shall, at a minimum:

(s) To satisfy the requirements of He-P 4035.55(p)(2) and (p)(3), spot-checks shall ensure proper operation of:

(5) Emergency “off” buttons~~;~~;

[\(6\) Radiation monitors used to indicate room exposures.](#)

Amend He-P 4035.56(b), effective 1-15-16 (Document #11011), cited and to read as follows:

He-P 4035.56 Radiation Surveys for Therapy Facilities.

(b) The licensee shall make the survey required by He-P 4035.56(a) at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

Amend He-P 4035.66(b) intro., (b)(2), (g), (i)(2), and (i)(4), effective 1-15-16 (Document # 11011) , so that (b) intro., (b)(2), (g), (i) intro., (i)(2) and (i)(4) are cited and read as follows:

He-P 4035.66 Training for the Oral Administration of Sodium Iodide I-131 and for the Parenteral Administration Requiring a Written Directive.

(b) Except as provided in He-P 4035.71, a physician who does not meet the requirement of He-P 4035.66(a) above shall: successfully complete 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.

(2) Have work experience, under the supervision of an authorized user who meets the requirements in He-P 4035.65, He-P 4035.66(a) and (b), He-P 4035.66(ed) and (de), He-P 4035.71, or equivalent agreement state, or Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements in He-P 4035.65(c) shall also have experience in administering dosages as specified in He-P 4035.65(c)(2)b.1. and-or (c)(2)b.2.

(g) Has obtained written attestation that the individual has satisfactorily completed the requirements in He-P 4035.66(d)(1) and (d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized user-under He-P 4035.35.

(i) Except as provided in He-P 4035.71, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(2) Is an authorized user under He-P 4035.59 or He-P 4035.69, or equivalent agreement state, or Nuclear Regulatory Commission requirements and meets the requirements in He-P 4035.66(g)(i)(4) – (i)(6) and (j); or

(4) An authorized user who does not meet the requirements of He P 4035.65(c) above, shall ~~shall~~ have successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required.

Ament He-P 4035.68(b), effective 1-15-16 (Document #11011), so that He-P 4035.68 intro. and (b) are cited and read as follows:

He-P 4035.68 Training for Use of Sealed Sources for Diagnosis. Except as provided in He-P 4035.71 the licensee shall require the authorized user using a diagnostic sealed source in a device specified in He-P 4035.39 to be a physician, dentist, or podiatrist who:

(b) Has completed 8 hours of instruction-classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device, including training in:

Amend He-P 4035.70(a) intro., (a)(5), and (c), effective 1-15-16 (Document # 11011), so that He-P 4035.70 intro., (a) intro., (a)(5) and (c) are cited and read as follows:

He-P 4035.70 Training for Authorized Medical Physicist. Excepted as provided in He-P 4035.71, the licensee shall require the authorized medical physicist to be an individual who:

(a) Is certified by a specialty board whose certification process has been recognized by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission, and who meets the requirements in He-P 4035.70~~(eb)~~(5) and (b)(6).

(5) Have obtained written attestation that the individual has satisfactorily completed the requirements in He-P 4035.70(b)(1)~~and~~, (b)(2) and (b)(6) or (b)(3)~~and~~, (b)(4) and (b)(6), and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in He-P 4035.70, He-P 4035.71, or an equivalent agreement state, or the Nuclear Regulatory Commission requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(c) In addition to the requirements of (b)(1) and (b)(2) above, each candidate for certification shall pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery.

Amend He-P 4035.74(c)(1)a. and b., effective 1-15-16 (Document #11011), so that He-P 4035.74 intro., (c) intro., (c)(1) intro., and (c)(1)a. and b. are cited and read as follows:

He-P 4035.74 Training for an Authorized Nuclear Pharmacist. Except as provided He-P 4035.71, the licensee shall require the authorized nuclear pharmacist to be a licensed pharmacist, as defined in RSA 318:1, VII, who:

(c) Have met the following requirements:

(1) Have completed 700 hours in a structured educational program consisting of both:

a. 200 hours of ~~didactic~~classroom and laboratory training in the following areas:

b. Supervised practical experience in a nuclear pharmacy involving the following:

APPENDIX

<u>RULE</u>	<u>STATUTE OR FEDERAL REGULATION IMPLEMENTED</u>
He-P 4035.13(b)(4)	10 CFR 35.40, 35.41, 35.100, 35.2040, 35.2041
He-P 4035.14(a) intro. & (a)(7)	10 CFR 35.3045
He-P 4035.35 intro.(b) & (c)	10 CFR 35.300
He-P 4035.38(a)	10 CFR 35.3047
He-P 4035.42(a),(c) intro. & (c)(2)	10 CFR 35.410, 35.2310
He-P 4035.44(a) intro. & (a)(2)	10 CFR 35.406, 35.2406
He-P 4035.55(b), (e), (r), and (s) intro., (s)(5), (s)(6)	10 CFR 35.642, 35.643, 35.645, 35.2642, 35.2643, 35.2645

He-P 4035.56(b)	10 CFR 35.652, 35.2652
He-P 4035.66(b) intro., (b)(2), (g), (i) intro., (i)(2), & (i)(4)	10 CFR 35.392, 35.394, 35.396
He-P 4035.68 intro. & (b) intro.	10 CFR 35.590
He-P 4035.70 intro., (a) intro., (a)(5) & (c)	10 CFR 35.51
He-P 4035.74 intro., (c) intro., (c)(1) intro., (c)(1)a. & b.	10 CFR 35.44